

Claim Rejections-35 U.S.C. §103

Edwards and VanTassel

Claims 1-4 and 6-15 stand rejected under 35 U.S.C. §103, as being obvious over U.S. Patent No. 6,071,280 issued to Edwards, et al. ("Edwards") in view of U.S. Patent No. 6,241,710 issued to VanTassel, et al. ("VanTassel"). Applicant respectfully traverses this rejection, since neither Edwards nor VanTassel, alone or in combination, discloses the combination of elements required by these claims.

In particular, as discussed in Applicant's previous response, VanTassel is not analogous prior art that can be properly used in combination with Edwards, since it is neither in the field of the inventors' endeavor nor is it reasonably pertinent to the particular problem with which the inventors were concerned. That is, the field of the inventors' endeavor is the ablative treatment of tumors, whereas the field that VanTassel is concerned with is the injection of medicaments into tissue, and the particular problem with which the inventors were concerned with is maximizing the size of therapeutic ablations, whereas the particular problem solved by VanTassel was providing a means for microinjecting controlled amounts of injectate to minimize leakage otherwise due to the rapid transfer of fluid.

Rather than directly responding to this, the Examiner has merely stated that VanTassel is analogous to the claimed invention because both are concerned with delivering fluid from a needle into tissue. However, the mere fact that a prior art reference and a claimed invention have commonalities is irrelevant to the determination of whether such prior art reference is analogous prior art. To find otherwise would completely eviscerate the requirement that a prior art reference be analogous for it to be considered in

an obviousness rejection, since, presumably, commonalities can always be found between an invention and a prior art reference used to reject the invention. What is relevant is whether the prior art is in the field of inventors' endeavor or reasonably pertinent to the particular problem with which the inventors were concerned. The Examiner has not provided any analysis with regard to this, and therefore, has not made out of *prima facie* case that VanTassel is an analogous prior art reference.

In the previous response, Applicant provided detailed reasoning supporting the conclusion that, even if VanTassel were an analogous prior art reference, there is no suggestion in VanTassel to modify the Edwards ablation device in the manner proposed by the Examiner, and that the Examiner improperly used Applicant's specification to make such a suggestion. The Examiner responded to this by merely stating that "using the knowledge generally available to one of ordinary skill in the art, it would have been obvious to modify Edwards in view of VanTassel because both references use pores in a needle shaft to deliver fluid into tissue." However, the fact that both Edwards and VanTassel deliver fluid through openings in a needle does not provide any suggestion that the Edwards ablation needle should be modified to include a porous material in the manner described in VanTassel. The fact that two prior art references have commonalities is not the proper inquiry in determining whether the prior art references can be properly combined.

The MPEP provides:

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the

combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." MPEP §2143.01(l.)(emphasis added).

The Examiner has not gone through this analysis, but has merely concluded that because VanTassel teaches a needle composed of a porous material for delivering fluid, that it would have been obvious to one of ordinary skill in the art to modify the Edwards device to have a sintered porous needle to provide an alternative way of allowing fluid to flow through the walls of the needle. However, the Examiner has not provided any reason why VanTassel would suggest, explicitly or implicitly, to one of ordinary skill in the art to make such a modification to the Edwards device. As required by the MPEP, a proper analysis requires the Examiner to determine what VanTassel teaches as a whole, including the problem to be solved, and whether those teachings can be fairly applied to Edwards.

However, because the teachings of VanTassel are irrelevant to tissue ablation, they cannot be fairly applied to Edwards. That is, as discussed in the previous response, VanTassel teaches the use of a porous hypodermic needle in order to microinject medicament into tissue, so that rapid fluid transfer is prevented (see col. 2, lines 18-32), and teaches nothing about RF tissue ablation or the effects of electrically conductive fluid perfusion on RF tissue ablation. The Examiner has shown absolutely no connection between Edwards and VanTassel other than they disclose mechanisms for delivering fluid.

As the Examiner surely knows, in determining whether such suggestion or motivation exists in the prior art, he cannot benefit from impermissible hindsight vision afforded by the claimed invention. In particular:

Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the

invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. (M.P.E.P. §2142) (emphasis added).

Because there is no suggestion in VanTassel to modify an ablation device, Applicant can only conclude that the Examiner has improperly used Applicant's specification to provide this suggestion. Rather than using Applicant's specification, it is requested that the Examiner only utilize the prior art in determining whether the claims at hand are obvious. Thus, without Applicant's specification, the Examiner is left with Edwards disclosing the need for an ablation device with infusion capabilities to improve the resulting tissue ablation, and VanTassel disclosing a hypodermic needle composed of a porous material to deliver a medicament in a controlled manner. There is simply no suggestion in VanTassel to modify the perfusion capability of ablation devices to improve tissue ablation.

Thus, Applicant submit that independent claims 1 and 10, as well as the claims depending therefrom (claims 2-4, 6-9, and 11-15), are not obvious over Edwards in view of VanTassel, and as such, respectfully request withdrawal of the §103 rejection of these claims.

Edwards, VanTassel, and Rangaswamy/Kirsch

Claims 5 and 16 stand rejected under 35 U.S.C. §103, as being obvious over Edwards, in view of VanTassel, in further view of either U.S. Patent No. 4,512,768 issued to Rangaswamy ("Rangaswamy") or U.S. Patent No. 6,503,225 issued to Kirsch, et al. ("Kirsch"). Applicant respectfully traverses this rejection, since none of Edwards, VanTassel, Rangawamy, or Kirsch, alone or in combination, discloses the combination of elements required by these claims.

In particular, as discussed above, it is believed that VanTassel cannot be properly combined with Edwards to form a basis for rejecting independent claims 1 and 10, or at the least, does not provide any teaching or suggestion to modify the Edwards ablation probe in the manner required by these claims, and neither Rangaswamy nor Kirsch supplements this failed teaching. Thus, Applicant submits that dependent claims 5 and 12 are not obvious over any proper combination of Edwards, VanTassel, Rangaswamy, and Kirsch, and as such, respectfully requests withdrawal of the §103 rejections of these claims.

Conclusion

Based on the foregoing, it is believed that all claims are allowable, and thus, a Notice of Allowance is respectfully requested. If the Examiner has any questions or comments regarding this amendment, the Examiner is respectfully requested to contact the undersigned at (949) 724-1849.

Respectfully submitted,

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Dated: May 15, 2006

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